INTERVIEW SUMMARY

The Examiner (Examiner McCormick) and her supervisor (Examiner Tate) are thanked for the courtesies extended during the telephonic interview conducted with the undersigned on January 18, 2007. During the interview, the rejection of claims for lack of enablement was discussed. Examiner Tate suggested that the term "prevention" be replaced with "reduce the risk" or "reduce the incidence."

REMARKS

Claims 1-24 have been canceled, without prejudice.

Claims 25-55 have been added. Support for these claims is found in the specification at, for example, page 1, lines 1-15; page 1, line 19 – page 2, line 2; page 3, lines 20-23; page 4, line 1 – page 5, line 26; and page 6, line 3 – page 8, line 7; in Examples 1-11; and in original claims 1-27. *See In re Gardner*, 177 USPQ 396, 397 (CCPA 1973) and MPEP §§ 608.01(o) and (l) (8th ed. Rev. 5, August 2006, pp. 600-92 and 600-84).

It is submitted that no new matter has been introduced by the foregoing amendments. Approval and entry of the amendments is respectfully solicited.

Enablement Rejection

Claims 1-13, 20, and 24 were rejected under 35 USC § 112, first paragraph, on the asserted grounds that "the specification does not enable any person skilled in the art ... to use the invention commensurate in scope with these claims." (Paper No. 0906 at 2.) In making the rejection, the Examiner conceded that "the specification [is] enabling for treating type I and type II diabetes, impaired glucose

tolerance or obesity." (*Id.*) The Examiner, however, asserted that the specification "does not reasonably provide enablement for prevention of diabetes impaired glucose tolerance and obesity." (*Id.*)

Claims 1-13, 20, and 24 have been canceled, without prejudice. Moreover, claims 25-55 do not recite "prevention." Instead, as suggested by the Examiner, claims 25-55 recite "reduce the incidence or risk..." or "reducing the incidence or risk...", as appropriate.

Accordingly, the rejection has been rendered moot and should be withdrawn.

Rejection under 35 USC § 102

Claims 1-2 were rejected under 35 USC § 102(b) as anticipated by Gorsek, US Patent No. 6,565,896 ("Gorsek".) (Paper No. 0906 at 5.)

For the reasons set forth below, the rejection, respectfully is traversed.

Gorsek discloses "Gamma Oryzanol, Guglipids, Beta Sitosterol, Green Tea extract, Artichoke extract, Grape Seed extract, Chromium, Pantethine, Policosanol, as well as other healthy filler ingredients." Col. 1, lines 30-33. Moreover, Gorsek discloses that "the key to the unique formulation is a combination of specific vitamins, minerals, herbs and nutrients. These essential components in the amounts provided uniquely contribute to a healthier cholesterol count in the bloodstream." Col. 1, lines 24-29.

In making the rejection, the Examiner asserted that Gorsek discloses "a composition which comprises EGCG and pantethine." (Paper No. 0906 at 5.)

Initially, we note that claims 1-2 have been canceled, without prejudice. For this reason alone, the rejection has been rendered moot and should be withdrawn.

As is well settled, anticipation requires "identity of invention." *Glaverbel Societe Anonyme v. Northlake Mktg. & Supply,* 33 USPQ2d 1496, 1498 (Fed. Cir. 1995). Each and every element recited in a claim must be found in a single prior art reference and arranged as in the claim. *In re Marshall*, 198 USPQ 344, 346 (CCPA 1978); *Lindemann Maschinenfabrik GMBH v. American Hoist and Derrick Co.,* 221 USPQ 481, 485 (Fed. Cir 1984).

Claims 25-55 have been added to further prosecution. Claims 25-55 recite compositions comprising "epigallocatechin gallate (EGCG) and phytanic acid," compositions comprising "epigallocatechin gallate (EGCG) and at least one additional active selected from the group consisting of pantethine, phytanic acid, and combinations thereof in admixture with a food or beverage," and methods for treating or reducing the incidence or risk of diabetes type 2 in a human "comprising administering to the human in need of such treatment a composition comprising epigallocatechin gallate (EGCG) and at least one additional active selected from the group consisting of pantethine, phytanic acid, and combinations thereof."

Gorsek discloses "a combination of specific vitamins, minerals, herbs and nutrients [that] in the amounts provided uniquely contribute to a healthier cholesterol count in the bloodstream." Col. 1, lines 24-29. This combination is ""Gamma Oryzanol, Guglipids, Beta Sitosterol, Green Tea extract, Artichoke extract, Grape Seed extract, Chromium, Pantethine, Policosanol, as well as other healthy filler ingredients." Col. 1, lines 30-33.

Gorsek simply does not disclose phytanic acid. Accordingly, Gorsek does not disclose a composition comprising EGCG and phytanic acid, as claimed.

Gorsek also does not disclose any food or beverage composition. Accordingly, Gorsek does not disclose anything in admixture with a food or beverage, much less, "epigallocatechin gallate (EGCG) and at least one additional active selected from the group consisting of pantethine, phytanic acid, and combinations thereof in admixture with a food or beverage," as claimed.

In addition, Gorsek is completely silent as to the treatment or reduction of the risk or incidence of type II diabetes. Accordingly, Gorsek does not disclose methods for treating or reducing the incidence or risk of diabetes type 2 in a human "comprising administering to the human in need of such treatment a composition comprising epigallocatechin gallate (EGCG) and at least one additional active selected from the group consisting of pantethine, phytanic acid, and combinations thereof."

The rejection does not demonstrate where in Gorsek each and every element of the claimed invention is disclosed. Accordingly, the rejection is deficient for failing to set forth a *prima facie* case for anticipation and should be withdrawn.

Rejections under 35 USC § 103

Claims 1-13 and 20-24 were rejected under 35 USC § 103(a) as being unpatentable over Chan, US Paten No. 5,922,756 ("Chan"), Fluehmann *et al.*, US Patent No. 6,784,207 ("Fluehmann"), and Cincotta *et al.*, US Patent No. 5,714,519 ("Cincotta"). (Paper No. 0906 at 6.)

For the reasons set forth below the rejection, respectfully, is traversed.

Chan discloses "a pharmacologically acceptable composition for inhibiting nitric oxide synthase (NOS) in a mammal ... include[ing] a catechin derivative and a pharmaceutically acceptable carrier, with the active agent present in the composition in an effective amount to inhibit NOS in the mammal." Col. 2, lines 31-37. Chan discloses EGCG as a catechin derivative useful in its invention. *See, e.g.*, claims 1 and 7. Chan also discloses that "an NO synthase enzyme may be involved in the pathophysiology of autoimmune and/or inflammatory conditions such as arthritis, rheumatoid arthritis and systemic lupus erythematosus and in insulin-dependent diabetes mellitus, and therefore, catechin derivatives may prove helpful in treating these conditions." Col. 3, lines 50-55.

Fluehmann discloses a "method for the treatment or prevention of preferably non-insulin dependent (NIDDM or so-called Type II) diabetes mellitus, and in particular to the use of phytanic acid derivatives for the treatment or prevention of NIDDM." Col. 1, lines 11-15. Fluehmann discloses that "NIDDM is the form of diabetes mellitus that occurs predominantly in adults in whom adequate production of insulin is available for use, yet a defect exists in insulin-mediated utilization and metabolism of glucose in peripheral tissues." Col. 1, lines 16-20. Fluehmann also discloses that phytanic acid and/or phytenic acid or derivatives thereof have the effect of "decreasing hyperinsulinaemia."

Cincotta discloses that an "object of the invention is to correct abnormalities in the glucose metabolism of a vertebrate animal, including humans, by administering an effective amount for: decreasing glucose intolerance; decreasing hyperinsulinemia; decreasing insulin resistance; and/or decreasing hyperglycemia of

pantethine or cysteamine." Col. 3. lines 60-65. Cincotta discloses that the "foregoing objects are accomplished by administering pantethine to a vertebrate subject in need of such treatment in an effective amount to reduce or ameliorate one or more aberrant indices associated with metabolism disorders (e.g., reducing glucose intolerance, reducing insulin resistance, reducing hyperglycemia, reducing hyperinsulinemia, ameliorating or treating Type II diabetes, and reducing levels of body fat)." Col. 4, lines 26-34.

In making the rejection, the Examiner asserted that Chan discloses that "EGCG is an inhibitor of nitric oxide synthase ... [and] that an NO synthase may be involved in diabetes and therefore, catechin derivative (including EGCG may be helpful in treating the condition." (Paper No. 0906 at 6.) The Examiner also asserted that Chan discloses "a method of treating diabetes which comprises administering to a mammal in need thereof EGCG." (*Id.*)

The Examiner acknowledged, however, that Chan differs from the presently claimed invention in that "Chan does not [disclose] that phytanic acid or pantethine are included in this composition." (*Id.* at 7.)

To fill the acknowledged gap, the Examiner relied upon Fluehmann as disclosing "a composition for the treatment of diabetes [including] phytanic acid, a method of making the composition, and a method for the treatment of diabetes using phytanic acid." (*Id.*)

Also to fill the acknowledged gap, the Examiner relied upon Cincotta as disclosing "a method for the treatment of diabetes [including] administering to a subject in need thereof an effective amount of pantethine." (*Id.*)

The Examiner then concluded that "it would have been obvious ... to admix EGCG, pantethine, phytanic acid, and mixtures thereof in the dosage forms and amounts instantly claimed in order to make a composition for the treatment of diabetes." (*Id.*)

Initially, we note that the Examiner bears the burden to set forth a *prima facie* case of unpatentability. *In re Glaug*, 62 USPQ2d 1151, 1152 (Fed. Cir. 2002); *In re Oetiker*, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992); and *In re Piasecki*, 223 USPQ 785, 788 (Fed. Cir. 1984). If the PTO fails to meet its burden, then the applicant is entitled to a patent. *In re Glaug*, 62 USPQ2d at 1152. When patentability turns on the question of obviousness, as here, the search for and analysis of the prior art by the PTO must include evidence relevant to the finding of whether there is a teaching, motivation, or suggestion to select and combine the documents relied on by the Examiner as evidence of obviousness. *McGinley v. Franklin Sports*, 60 USPQ2d 1001, 1008 (Fed. Cir. 2001). This factual inquiry into whether to combine documents must be thorough and searching.

As is well settled, the teaching, motivation, or suggestion to combine "***must be based on objective evidence <u>of record</u>***." *In re Lee*, 61 USPQ2d 1430, 1433 (Fed. Cir. 2002). Moreover, the Examiner is required to demonstrate ***where*** in the cited documents there is a suggestion which would have "strongly motivated" one to do as the applicants claim. *Ex parte Graselli*, 231 USPQ 393, 394 (Bd. App. 1986). The type of motivation, which would have "***impelled***" one to do so (*Ex parte Levengood*, 28 USPQ2d 1300, 1301-02 (BPAI 1993)), and the type of suggestion that the changes to

the cited documents "***should***" be made. *Ex parte Markowitz*, 143 USPQ 303, 305 (Bd. App. 1964).

However, no such motivation can be found in the cited documents.

Chan discloses "a pharmacologically acceptable composition for inhibiting nitric oxide synthase (NOS) in a mammal ... include[ing] a catechin derivative and a pharmaceutically acceptable carrier, with the active agent present in the composition in an effective amount to inhibit NOS in the mammal." Col. 2, lines 31-37. Chan discloses EGCG as a catechin derivative useful in its invention. *See, e.g.*, claims 1 and 7. Chan discloses that the catechin derivatives "may be useful to inhibit NO synthesis in patients suffering from inflammatory conditions in which an excess of NO contributes to the pathophysiology of the condition, such as adult respiratory distress syndrome and myocarditis, for example." Col. 3, lines 45-49. The only reference to diabetes in Chan is to type 1 diabetes (insulin-dependent diabetes mellitus):

> an NO synthase enzyme may be involved in the pathophysiology of ***autoimmune and/or inflammatory conditions*** such as arthritis, rheumatoid arthritis and systemic lupus erythematosus and in ***insulin-dependent diabetes mellitus***, and therefore, catechin derivatives may prove helpful in treating these conditions. Col. 3, lines 50-55.

In type 1 diabetes, the pancreas no longer makes insulin, because the beta cells have been destroyed. Accordingly, the body does not produce its own insulin, resulting in hypoinsulinaemia.[1] Thus, an exogenous source of insulin is generally required to utilize glucose from food. *See, e.g.*, the American Diabetes Association website (http://www.diabetes.org).

Fluehmann discloses a "method for the treatment or prevention of preferably ***non-insulin dependent (NIDDM or so-called Type II) diabetes mellitus***, and in particular to the use of phytanic acid derivatives for the treatment or prevention of NIDDM." Col. 1, lines 11-15. Fluehmann discloses that "NIDDM is the form of diabetes mellitus that occurs predominantly in adults ***in whom adequate production of insulin is available for use,*** yet a defect exists in insulin-mediated utilization and metabolism of glucose in peripheral tissues." Col. 1, lines 16-20. Fluehmann also discloses that phytanic acid and/or phytenic acid or derivatives thereof have the effect of "***decreasing hyperinsulinaemia***."[2]

Cincotta discloses that an "object of the invention is to correct abnormalities in the glucose metabolism of a vertebrate animal, including humans, by administering an effective amount for: decreasing glucose intolerance; ***decreasing hyperinsulinemia***; decreasing insulin resistance; and/or decreasing hyperglycemia of pantethine or cysteamine." Col. 3. lines 60-65. Cincotta discloses that the "foregoing objects are accomplished by administering pantethine to a vertebrate subject in need of such treatment in an effective amount to reduce or ameliorate one or more aberrant indices associated with metabolism disorders (e.g., reducing glucose intolerance, reducing insulin resistance, reducing hyperglycemia, ***reducing hyperinsulinemia***, ***ameliorating or treating Type II diabetes***, and reducing levels of body fat)." Col. 4, lines 26-34. In the only reference to type 1 diabetes, Cincotta contrasts it with type 2 diabetes:

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[1] Hyperinsulinaemia is defined as "an abnormally low concentration of insulin in the blood." Merriam-Webster's Medical Dictionary, Merriam-Webster, Inc. (2002).

> In insulin-dependent (IDDM or Type I) diabetes, wherein the pancreas produces little or no insulin, insulin must be injected daily. In noninsulin-dependent (NIDDM or Type II) diabetes ***the pancreas retains the ability to produce insulin, in fact it may produce higher than normal amounts of insulin (hyperinsulinemia)***, but due to a cellular resistance to insulin, the amount of insulin is relatively insufficient. Col. 1, lines 47-54.

To summarize, Chan discloses that a catechin derivative, such as EGCG, may help in the treatment of autoimmune and inflammatory disorders, including type 1 diabetes. Fluehmann and Cincotta disclose that phytanic acid (and derivatives) or pantethine, respectively, may be used to decrease hyperinsulinaemia and treat type 2 diabetes. Thus, Chan provides a way to increase the production of insulin in those who lack the ability to produce insulin. And, Fluehmann and Cincotta provide a way to decrease blood levels of insulin in those who have insulin resistance.

Based, on the disclosures of Chan, Fluehmann, and Cincotta it would defy common sense to administer EGCG and phytanic acid or pantethine concomitantly. According to Chan, EGCG would potentially increase insulin blood levels in type 1 diabetics. According to Fluehmann and Cincotta phytanic acid and pantethine, respectively, work to decrease hyperinsulinaemia in type 2 diabetics. Thus, according to the cited documents, the administration of EGCG concomitantly with phytanic acid or pantethine would result in a treatment that is self-defeating.

Thus, there is nothing in the cited documents that discloses or suggests their combination as suggested by the Examiner. In fact, the cited documents disclose

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[2] Hypoinsulinaemia is defined as "the presence of excess insulin in the blood." Merriam-Webster's Medical Dictionary, Merriam-Webster, Inc. (2002).

that such combination would be futile. Accordingly, the rejection fails to present a *prima facie* case for obviousness and should be withdrawn.

Claim 14 was rejected under 35 USC § 103(a) as being unpatentable over Chan, Fluehmann, Cincotta, Fischer, US Patent No. 5,599,835 ("Fischer"), Pistolesi, WO 02/052955 A1 ("Pistolesi"), and Eriksson *et al.*, Biofactor, vol. 9, pp. 315-318 (1999) ("Eriksson"). (Paper No. 0906 at 8.)

For the reasons set forth below the rejection, respectfully, is traversed.

Chan, Fluehmann, and Cincotta are summarized above.

Fischer discloses a "method for the management of a metabolic disorder expressed as diabetes mellitus, which is a syndrome of impaired carbohydrate, protein and fat metabolism secondary to insufficient secretion of insulin." Col. 2, lines 54-57. Fischer discloses that the "use of DL-lipoic acid in co-administration with other nutrients that are also essential to the multi-enzyme reactions of the pyruvate dehydrogenase complex ... [and] a composition as a modular-formula medical food for oral administration [for] the treatment, management or correction of a metabolic disorder that is indicative of diabetes mellitus." Col. 2, lines 58-65.

Pistolesi discloses "pharmaceutical and dietary compositions ... for both preventing and treating aging processes and related conditions" including diabetes. p. 1. Pistolesi further discloses that its "compositions [include]:

a) a lipidic mixture rich in polyunsaturated fatty acids, preferably docosahexaenoic acid (DHA), eicosapentaenoic acid (EPA), conjugated linoleic acids (CLA) and y-linolenic acid, and antioxidant vitamins, in combination with at least two of the following components:

b) one or more terpenes, selected from monoterpenes and/or sesquiterpenes, triterpenes, lactonic terpenes, but preferably monoterpenes or sesquiterpenes,

c) 1-piperoylpiperidine (in pure form and/or purified extracts or fractions containing it enriched in black pepper) and/or capsaicin and analogues thereof, preferably 1- piperoylpiperidine,

d) one or more polycosanols and/or polycosanolic acids. p. 1.

Eriksson discloses that Coenzyme Q_{10} has "no major effect ... on metabolic parameters in diabetics." p. 318. Eriksson concluded "that treatment with CoQ_{10} is well tolerated among type 2 diabetics and that CoQ_{10} does not interfere with the glycemic control, i.e., CoQ_{10} is neutral with respect to diabetes control. Therefore, CoQ_{10} may be used safely in type 2 diabetes, and especially in association with arterial hypertension, coronary artery disease or heart failure CoQ_{10} may contribute to potential long term benefits in the treatment of type 2 diabetic patients." *Id.*

In making the rejection, the Examiner asserted that Chan, Fluehmann, and Cincotta disclose "composition and methods for the treatment of diabetes comprising EGCG, phytanic acid and pantethine and are relied upon for the reasons set forth above." (Paper No. 0906 at 8.)

The Examiner apparently recognized that the suggested combination of Chan, Fluehmann, and Cincotta differs from the presently claimed invention in that the combination does not disclose a composition containing lipoic acid, policosanol and coenzyme Q-10.

To fill this gap, the Examiner relied upon Fischer as disclosing "lipoic acid as a treatment for diabetes ... [and] a method for the treatment of diabetes comprising administering to a person in need thereof an effective amount of a medicinal food [including] lipoic acid." (*Id.*)

Also to fill this gap, the Examiner relied upon Pistolesi as disclosing "a composition for treating aging processes and related [conditions], including diabetes ... the composition [including] policosanol." (*Id.* at 9.)

In addition, to fill this gap, the Examiner relied on Eriksson as disclosing "the use of coenzyme Q_{10} in a treatment for diabetes." (*Id.*)

The Examiner then concluded that "it would have been obvious ... to combine the ingredients [disclosed] by Chan, Fluehmann, Cincotta, Fischer, Pistolesi, and Eriksson to make a food or beverage [including] EGCG, pantethine, phytanic acid, lipoic acid, policosanol and coenzyme Q_{10}." (*Id.*)

As noted above, when patentability turns on the question of obviousness, as here, the search for and analysis of the prior art by the PTO must include evidence relevant to the finding of whether there is a teaching, motivation, or suggestion to select and combine the documents relied on by the Examiner as evidence of obviousness. *McGinley*, 60 USPQ2d at 1008. And, this teaching, motivation, or suggestion to combine "***must be based on objective evidence of record***." *Lee*, 61 USPQ2d at 1433.

As discussed above, Chan provides a way to increase the production of insulin in those who lack the ability to produce insulin. And, Fluehmann and Cincotta provide a way to decrease blood levels of insulin in those who have insulin resistance.

Based, on the disclosures of Chan, Fluehmann, and Cincotta it would defy common sense to administer EGCG and phytanic acid or pantethine concomitantly. According to Chan, EGCG would potentially increase insulin blood levels in type 1 diabetics. According to Fluehmann and Cincotta phytanic acid and pantethine,

respectively, work to decrease hyperinsulinaemia in type 2 diabetics. Thus, according to the cited documents, the administration of EGCG concomitantly with phytanic acid or pantethine would result in a treatment that is self-defeating.

Nothing in the newly cited documents, *e.g.*, Fischer, Pistolesi, and/or Eriksson offers anything to close this fatal gap in the combination of Chan, Fluehmann, and Cincotta. Thus, as with the previous rejection, there is nothing in the cited documents that discloses or suggests their combination as suggested by the Examiner. In fact, the cited documents disclose that such combination would be futile. Accordingly, the rejection fails to present a *prima facie* case for obviousness and should be withdrawn.

Obvious-Type Double Patenting Rejection

Claim 20 was been provisionally rejected under the judicially created doctrine of obviousness-type double patenting. (Paper No. 0906 at 3.) In making the rejection, the Examiner alleged that claim 20 of the instant application is "unpatentable over claims 10-13 of copending Application No. 10/766,118." (*Id.*)

Claims 21-24 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting. (Paper No. 0906 at 4.) In making the rejection, the Examiner alleged that claims 21-24 of the instant application are "unpatentable over claims 1-2, 4, [and] 7-18 of copending Application No. 10/573,222." (*Id.*)

Claims 1-14 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting. (Paper No. 0906 at 4.) In making the

rejection, the Examiner alleged that claims 1-14 of the instant application are "unpatentable over claims 1-8 of copending Application No. 10/588,042." (*Id.*)

Claims 1-14 and 20-24 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting. (Paper No. 0906 at 4.) In making the rejection, the Examiner alleged that claims 1-14 and 20-24 of the instant application are "unpatentable over claims 1-9 of copending Application No. 10/536,374." (*Id.*)

Claims 1-14, 20, and 22-24 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting. (Paper No. 0906 at 4.) In making the rejection, the Examiner alleged that claims 1-14, 20, and 22-24 of the instant application are "unpatentable over claims 1-8, 18-20 and 26-27 of copending Application No. 10/525,348." (*Id.*)

Claims 1-14 and 20-24 have been canceled, without prejudice. Thus, all of the provisional double patenting rejections have been rendered moot and should be withdrawn.

Accordingly, for the reasons set forth above, entry of the amendments, withdrawal of the rejections, and allowance of the claims are respectfully requested. If the Examiner has any questions regarding this paper, please contact the undersigned.

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on April 13, 2007.

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